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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/570,485

03/03/2006

Eishin Kato

80110(302725)

9937

21874

7590

07/06/2009

EDWARDS ANGELL PALMER & DODGE LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

07/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/570,485	<b>Applicant(s)</b> KATO ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/3/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment in the reply filed on 4/30/09 is acknowledged, with the additional newly added Claims 16-20. Claims 1-20 are pending. Claim 6 is withdrawn. **Claims 1-5, and 7-20 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

It is noted that the correct status of claim 6 should be "withdrawn", instead of "original".

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, and 10-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Boralle et al (Oligostibenoids from *Gnetum venosum*, *Phytochemistry*, 34 (5): 1403-1407, 1993), in view of Berry (Cyclopropene fatty acids in *Gnetum gnemon* (L.) seeds and leaves, *Journal of the Science of Food and Agriculture*, (1980) Vol. 31, No. 7, pp. 657-662).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 12/5/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

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Boralle et al teach extracting the seeds of *Gnetum venosum* by exhaustive percolation with EtOH (thus a solid-liquid mixture, an organic solvent, a polar organic solvent). The solution was evaporated (thus solid content is removed) and the residue partitioned between  $\text{CHCl}_3$ , and MeOH. The solvents were evaporated. The residue of the  $\text{CHCl}_3$  solution was fractionated first by CC and finally by TLC. All compounds were purified by HPLC (see title; page 1407, 1st column, 5th paragraph).

Since the reference teaches extracting the claimed material *Gnetum* seeds with the claimed solvent ethanol, it is deemed that the extracts would intrinsically have the claimed absorption spectrum and Rf value.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as cosmetic or seasoning products. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Boralle et al do not explicitly teach using 15-80% or 50% EtOH to extract *Gnetum* seeds, nor do Boralle et al teach mixing *Gnetum* extract to vegetable extract.

Berry teaches seed kernels of *Gnetum gnemon*, eaten after boiling or roasting the nuts (see Abstract). Berry teaches that nuts are starchy, astringent and rather bitter in taste that persists even after cooking. The kernels are eaten after removing the shell from the roasted or boiled nuts. They are mashed, moulded into cakes, biscuits or pounded flat into 'keropok' (crisps) which are dried in the sun and deep-fried in oil prior to consumption (page 44, 1st paragraph). Berry also teaches the young leaves of the plant are consumed as vegetable (page 44, 2<sup>nd</sup> paragraph).

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It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adjust the concentration of EtOH to extract the Gnetum seeds from Boralle et al according to the polarity of the constituent in the seeds that is desired to isolate, as the result-effective adjustment in conventional working parameters (e.g., determining an appropriate concentration of the solvent) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons,

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there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the concentration of ethanol, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of the solvent, which would have been routinely determined and optimized in the pharmaceutical art.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to boil the *Gnetum gnemon* kernels (the same as seeds) and leaves (thus mixing with vegetable extract) together (thus a polar extract) and then to consume since Berry teaches both the kernel and leaves can be eaten.

Since both of the references teach *Gnetum* seed, one of ordinary skill in the art would have been motivated to make the modifications and combine the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 5, 7-9, and 16-20 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Boralle et al (Oligostibenoids from *Gnetum venosum*, *Phytochemistry*, 34 (5):

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1403-1407, 1993), in view of Berry (Cyclopropene fatty acids in *Gnetum gnemon* (L.) seeds and leaves, *Journal of the Science of Food and Agriculture*, (1980) Vol. 31, No. 7, pp. 657-662), and further in view of Iliya et al (Iliya et al, Stilbene derivatives from two species of Gnetaceae, *Chem. Pharm. Bull.* 50 (6) 796-801 (2002)).

This is a new rejection necessitated by the Applicant's amendment filed on 4/30/09.

Boralle et al teach extracting the seeds of *Gnetum venosum* by exhaustive percolation with EtOH (thus a solid-liquid mixture, an organic solvent, a polar organic solvent). The solution was evaporated (thus solid content is removed) and the residue partitioned between  $\text{CHCl}_3$ , and MeOH. The solvents were evaporated. The residue of the  $\text{CHCl}_3$  solution was fractionated first by CC and finally by TLC. All compounds were purified by HPLC (see title; page 1407, 1st column, 5th paragraph). Boralle et al also teach *Gnetum venosum* contains, besides the stilbenes resveratrol and reponitigentin, oxidative stilbene oligomers such as the dimer gnetic C and the tremers gnetic E, gnetic J and gnetic K (see Abstract).

Since the reference teaches extracting the claimed material *Gnetum* seeds with the claimed solvent ethanol, it is deemed that the extracts would intrinsically have the claimed absorption spectrum and Rf value.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as cosmetic or seasoning products. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

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Boralle et al do not explicitly teach using 15-80% EtOH or 50% EtOH to extract *Gnetum gnemon* seeds, nor do Boralle et al teach mixing *Gnetum* extract to vegetable extract, or an aged *Gnetum* extract or more than 12 h.

Iliya et al teach the family of Gnetaceae is known to contain stilbenoids. The leaves and the fruits are used as food in many parts of tropics. Five new stilbenoids isolated from two species of Gnetaceae. Gnemonols A and B were obtained from the root of *Gnetum gnemon*. Gnemonol C, gnemonoside E and gnetal were isolated from both species (page 796, 1<sup>st</sup> column, 1<sup>st</sup> paragraph).

Berry teaches seed kernels of *Gnetum gnemon*, eaten after boiling or roasting the nuts (see Abstract). Berry teaches that nuts are starchy, astringent and rather bitter in taste that persists even after cooking. The kernels are eaten after removing the shell from the roasted or boiled nuts. They are mashed, moulded into cakes, biscuits or pounded flat into ‘keropok’ (crisps) which are dried in the sun (thus an aged *Gnetum* extract for more than 12 hours) and deep-fried in oil prior to consumption (page 44, 1<sup>st</sup> paragraph). Berry also teaches the young leaves of the plant are consumed as vegetable (page 44, 2<sup>nd</sup> paragraph).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use ethanol (thus polar solvent) to extract stilbene from the seeds or seeds containing material from *Gnetum gnemon* since Boralle et al teach that it is from the seeds of the same genus *Gnetum*, stilbene was isolated. Further more, Iliya et al teach the family of Gnetaceae is known to contain stilbenoids, and stilbene was isolated from the root of claimed species *Gnetum gnemon*. Therefore, an artisan of ordinary skill at the time of the invention would have had a reasonably expected that the seeds or seed containing material of *Gnetum*



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gnemon has the sought properties, which are stilbenes, namely gnetin C, gnemonocide A and Gnemonocide D, and it is deemed that the claimed material stilbenes would necessarily have the claim designated antimicrobial and/or antioxidative function.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to adjust the concentration of EtOH to extract the Gnetum seeds from Boralle et al according to the polarity of the constituent in the seeds that is desired to isolate, as the result-effective adjustment in conventional working parameters (e.g., determining an appropriate concentration of the solvent) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum

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combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the concentration of ethanol, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of the solvent, which would have been routinely determined and optimized in the pharmaceutical art.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to boil the Gnetum gnemon kernels (the same as seeds) and leaves (thus mixing with vegetable extract) together (thus a polar extract) and then to consume since Berry teaches both the kernel and leaves can be eaten.

Since all of the references teach using plant materials from genus Gnetum, one of ordinary skill in the art would have been motivated to make the modifications and combine the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments regarding the 102 rejections have been fully considered and are persuasive. The 102 rejections have been withdrawn.

Applicant's arguments regarding claims 1, 5, and 7-9 in the 103 rejection have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Iliya et al.

### **Conclusion**

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Flood C. Michele/

Primary Examiner, Art Unit 1655